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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,729	07/15/2003	Emilio J.A. Roldan	3524.015	7038

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,729	ROLDAN ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,33,35-37,40-45 and 47-65* is/are pending in the application.

4a) Of the above claim(s) *47-53 and 55-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,33,35-37,40-45,54 and 58-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2009 has been entered.

Any rejection or objection not expressly repeated has been withdrawn. The arguments presented with the RCE will be addressed insofar as they apply to the current rejections set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 32, 35 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Beek et al (WO 97/02827).

Van Beek discloses the use of 1-amino-3-(N,N-dimethylamino)-propylidene-1,1-bisphosphonic acid (NH_2-OPD) for the prevention or treatment of all forms of osteoporosis, arthritis and periodontal diseases in combination with other bone active molecules. See page 3, last paragraph to page 4, line 8; page 5, 2nd full paragraph; and reference claims 5-10. Osteoporosis, arthritis and periodontal diseases are considered bone disorders.

Applicant's arguments filed May 11, 2009 have been fully considered but they are not persuasive. Applicant argues that Van Beek discloses that NH_2-OPD can be used for "carriers for other bone active molecules, which is different from the treatment of bone disorder, thus Van Beek et al do not anticipate." The examiner respectfully disagrees. While the reference teaches that NH_2-OPD acts as a carrier for the other therapeutic molecules, the circumstance in which said therapeutic molecules and NH_2-OPD are administered is for the prevention/treatment of bone disorders, such as osteoporosis. The step of the method is accomplished thereby anticipating the method.

Claims 32, 35 and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Beek et al (US 5,990,098)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Van Beek discloses the use of NH_2-OPD for the prevention or treatment of all forms of osteoporosis, arthritis and periodontal diseases in combination with other bone active molecules. See col 2, lines 21-48; col 3, 15-32; and reference claims 11-18. Osteoporosis, arthritis and periodontal diseases are considered bone disorders.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 33, 35-37, 42-45, 54, 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Beek et al (WO 97/02827).

Van Beek teaches as set forth above. The reference is silent regarding dosages and the particularly recited sub-categories of patients, "healthy patients," "humans at or above the age of 40 years" or "a child" or to a child.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to select any human patient for the administration of NH_2-OPD for maintaining a healthy bone structure with a reasonable expectation of success. As discussed above, Van Beek teaches the administration of NH_2-OPD with bone active molecules for the prevention of bone diseases, such as osteoporosis. In the absence of unexpected results, it would be within the scope of the artisan to select any appropriate patient for such treatment. It would be further within the scope of the artisan to determine appropriate dosages through routine experimentation. Applicant has demonstrated not demonstrated any criticality in a particular dosage range.

Claims 40, 42-45, 54, 58-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ringe (Calcif. Tissue Int., 1997) in view of Van Beek et al (WO 97/02827).

Ringe teaches the treatment of active vitamin D metabolites for the treatment of glucocorticoid (corticosteroid)-induced osteoporosis. See entire reference. The reference is silent regarding the administration of NH_2-OPD.

Van Beek teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a vitamin D metabolite in combination with NH_2-OPD for the treatment of corticosteroid-induced osteopenia/osteoporosis (a metabolic bone disease) with a reasonable expectation of success. Van Beek had taught this combination for the treatment of osteoporosis generally. Therefore one of ordinary skill would expect success in treating this particular type of osteoporosis in an adult or child with a reasonable expectation of success. It

would be further within the scope of the artisan to determine appropriate dosages through routine experimentation. Applicant has demonstrated not demonstrated any criticality in a particular dosage range.

Claims 41-45, 54, 58-62, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Omeroglu et al (Arch. Orthop. Trauma Surg., 1997) in view of Van Beek et al (WO 97/02827).

Omeroglu teaches the treatment of a bone fracture by placement of Steinmann pins. The post-treatment of this fracture is the administration of vitamin D_3. The dosage is 50,000 IU/kg. (10,000 IU = 250 μg) See "Materials and methods" at page 271. The reference is silent regarding the administration of NH_2-OPD.

Van Beek teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add NH_2-OPD to the vitamin D_3 post-treatment of a bone fracture with a reasonable expectation of success because Van Beek had taught that NH_2-OPD is useful in transporting bone active agents, such as vitamin D. With respect to particular dosages of NH_2-OPD, as discussed above, it would be within the scope of the artisan to determine an appropriate dosage through routine experimentation.

Claims 32, 35, 36, 40-45, 54 and 58-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (Bone, 1995) in view of Van Beek et al (WO 97/02827).

Li teaches the administration of parathyroid hormone (PTH) alone, or in combination with an antiresorptive agent, to OVX rats as a model for the treatment/prevention of osteoporosis. See entire reference. The reference is silent regarding the administration of NH_2-OPD.

Van Beek teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to add NH_2-OPD to the PTH for the prevention/treatment of osteoporosis with a reasonable expectation of success because Van Beek had taught that NH_2-OPD is useful in transporting bone active agents, such as OTH. With respect to particular dosages of NH_2-OPD, as discussed above, it would be within the scope of the artisan to determine an appropriate dosage through routine experimentation. Because osteoporosis is incurable, it would be obvious to continue treatment throughout the life of the patient.

With respect to claim 40, it would to obvious to administer the PTH in combination with NH_2-OPD for the prevention/treatment of osteoporosis regardless of the cause with a reasonable expectation of success because the OVX model for osteoporosis is a general one.

With respect to claim 41, Li describes the PTH treatment as particularly suited for the treatment of more established disease. Therefore, it would be obvious to administer PTH in combination with NH_2-OPD subsequent to an earlier treatment, such as one comprising an antiresorptive agent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 60-65 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 recites the limitation "wherein an anti-resorptive activity is not desired." However, it is unclear as to what scope this encompasses. It could be that there is some diagnostic criterion (or criteria) wherein antiresorptive activity is contraindicated, but there is no such situation described. Alternatively, it could be that this limitation resides solely in the thoughts of the practitioner. Therefore, one of ordinary skill would not be apprised of the metes and bounds of the claim.

Claim 60 recites the limitation "until the patient is free of the bone disorder." However, the scope of "bone disorder" encompasses a great variety of incurable diseases, including some of the ones particularly recited in claim 62, such as Paget's disease. Therefore, it is not clear if Applicant intends an actual curative method or treatment of the chronic disease until the patient dies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41 and 60-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Claim 41 recites the limitation "wherein antiresorptive treatment is not desired." As discussed above, a possible construction of this limitation is that there is some diagnostic criterion (or criteria) wherein antiresorptive activity is contraindicated. However, if this is the proper construction, there is no description of this situation.

Claim 60 recites the limitation "until the patient is free of the bone disorder." This limitation is newly added to the claim, and the examiner does not find any support for this limitation in the disclosure as filed. Applicant is requested to point out the written description support for this limitation.

Claims 32, 33, 35-37, 40-45, 54 and 58-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prevention/treatment of some set of the recited disease, under some circumstances, as discussed below, does not reasonably provide enablement for the full scope of treatment/prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

The scope of bone disorders is immense. The term includes common bone disorders such as Paget's disease ("osteitis deformans"), osteopenia, and osteoporosis. It also includes dysplasias including osteogenesis imperfecta (which is classified into 4 forms), osteopoikilosis, osteopetrosis (Albers-Schoenberg disease), achondroplasia, fibrous dysplasia, osteochondromatosis, Caffey's disease, Lenz-Majewski syndrome, melorheostosis, pyknodysostosis, sclerosing diaphyseal dysplasia (Camurati-Engelmann disease), spondyloepiphyseal dysplasia, Nail-patella syndrome, and many others. There are also the osteochondrodysplasias, including achondroplasia, chondrodysplasia punctata, chondrodysplasia punctata (which comes in Conradi-Hünermann form or rhizomelic form), chondrodysplasia punctata, chondroectodermal dysplasia (Ellis-van Creveld syndrome), diastrophic dysplasia, hypochondroplasia, mesomelic dysplasia (which some in multiple forms, including Nievergelt, and Langer), metaphyseal chondrodysplasia (which comes in several forms, including Jansen, Schmid, McKusick forms), multiple epiphyseal dysplasia, pseudoachondroplasia, and spondyloepiphyseal dyspla. There are also the craniotubular dysplasias: metaphyseal dysplasia (Pyle's disease), craniometaphyseal dysplasia, and frontometaphyseal dysplasia. Somewhat related to these are the craniotubular hyperostoses: endosteal hyperostosis (van Buchem's syndrome), sclerosteosis and diaphyseal dysplasia (Camurati-Engelmann disease). There are forms of osteosclerosis, including Albers-Schönberg disease, osteopetrosis with precocious

manifestations, osteopetrosis with renal tubular acidosis and pyknodysostosis. It includes dense bones disorders, including axial osteomalacia, fibrogenesis imperfecta ossium, sarcoidosis and tuberous scelrosis. Other bone disorders include Torus palatinus, cleidocranial dysostosis, coxa plana, Hand-Schueller-Christian disease, brachydactyly, calcium pyrophosphate deposition disease (CPPD), Wormian bones, tibia vara (Blount disease), cervical spine fusion (ankylosis), Crouzon syndrome, hereditary multiple exostosis, idiopathic scoliosis, slipped capital femoral epiphysis (SCFE), celery-stalk metaphyses, Bankart deformity, Ollier disease, craniosynostosis, Erlenmeyer flask deformity, ivory vertebral body, spheroid calcification, acro-osteolysis, Caffey disease, cherubism, Sever disease, Sprengel deformity, Letterer-Siwe disease, Pott's disease, Scheuermann disease, sabre-shin deformity, basilar invagination, degenerative disc disease, block vertebra, Kohler disease, hyperostosis frontalis interna, diastrophic dwarfism, posterior vertebral scalloping, multicentric reticulohistiocytosis, osteitis fibrosa, vertebra plana, Hill-Sachs deformity, Kienbock disease, spontaneous osteolysis, osteochondritis dissecans, and many, many more. There are the osteochondroses, which include Infrapatellar Tendinitis (Sinding-Larsen-Johansson Syndrome), Köhler's bone disease, Legg-Calvé-Perthes disease, Osgood-Schlatter disease, Scheuermann's disease, Panner disease, and others. Osteomyelitis comes in a number of forms and can be secondary to a contiguous focus of infection or secondary to vascular insufficiency, and there is chronic osteomyelitis, including the formation of sequestrum (dead bone) associated with avascular necrosis of bone. Included also are bone tumors, including osteosarcomas (osteoblastic, chondroblastic, fibroblastic, telangiectatic, and others), hemangiosarcoma, periosteal chondrosarcoma, periosteal fibrosarcoma, maxillary fibrosarcoma, parosteal osteosarcoma, periosteal osteosarcoma, malignant mesenchymoma, liposarcoma,

synovial sarcoma, osteochondroma, hemangioma, myxoma of the jaw, ossifying fibroma, osteoma, giant cell tumor of bone, multiple myeloma, solitary myeloma, reticulum cell sarcoma, malignant fibrous histiocytoma, desmoblastic fibroma of the bone, periosteal fibroma, lipoma, hemangioendothelial sarcoma, Ewing's sarcoma, chondroblastoma, and multilobular tumor of bone. There are also tumor-like lesions, including osteoid osteoma, non-osteogenic fibroma, benign osteoblastoma, solitary bone cyst, juxtacortical bone cyst, myositis ossificans, villonodular synovitis and epidermoid cyst of the phalanx. There are also secondary malignant deposits in bone.

Owing to the extreme variety of disorders of the bone (including bone marrow), there is no such thing as a "representative" or "typical" bone disorder. Things like e.g. bone sarcomas, idiopathic scoliosis, dense bones disorders, osteomyelitis, and cherubism really have almost nothing in common except being bone disorders. Hence, there is no expectation of success in using one particular agent for the treatment/prevention of such a vast and disparate scope of diseases.

Even the narrower dependent claims (43 and 62) recite, in addition to particular disorders, "metabolic bone disease" which is an umbrella term including disparate disorders such as osteoporosis and multiple myeloma.

With the exception of "metabolic bone disease" and the similarly broad "ossification disorder," the claims are enabled for the *treatment* of the particular conditions set forth in claims 43 and 62. However, the treatment is enabled *only* when in combination with some known bone-active agent. Furthermore, claim 62 is problematic depending on the construction of claim 60.

Although some of the recited diseases, such as Paget's disease are *treatable*, they are not curable, as appears to be intended with the limitation "until the patient is free of the bone disorder."

With respect to *prevention*, the claims are enabled for osteoporosis and the various types of osteopenia. As with treatment, prevention is enabled *only* when in combination with some known bone-active agent.

The scope of these claims includes the treatment/prevention of various disorders with NH_2-OPD alone. However, generally, the basis for the treatment/prevention of the enabled diseases as taught in the art is either the inhibition of resorption or enhanced bone formation. See review in Rodan et al (Science, 2000). Applicant has demonstrated that NH_2-OPD does not have antiresportive activity. However, there is no demonstration that NH_2-OPD has any capacity to induce bone formation. The only treatment data is drawn to the effect of NH_2-OPD on osteoblasts. It is noted that the disclosure compares the effect of NH_2-OPD on osteoblasts with that of $1,25(OH)_2D_3$. Although both NH_2-OPD and $1,25(OH)_2D_3$ demonstrate changes in Ca^{2+} concentration and induction of osteocalcin in blastocysts (same direction but not same magnitude), this is not seen to be an accepted model for the treatment of bone disorders. The effect of vitamin D in bones is much more complex. See, for example Akesson et al (Calcif. Tissue Int., 1997) at "Vitamin D Action" the section bridging pages 100 and 101. These *in vitro* data would not lead one of ordinary skill to expect that this compound alone would be enabled for the prevention/treatment methods recited in the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32, 33, 35-37, 42-45, 58 and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 5,990,098.

Claims 32, 40, 54 and 60-65 are rejected over reference claim 14 in view of Ringe (Calcif. Tissue Int., 1997).

Claims 32, 41, 54 and 60-65 are rejected over reference claim 14 in view of Omeroglu et al (Arch. Orthop. Trauma Surg., 1997).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Reference claim 12 is drawn to the diagnosis, prophylaxis and/or treatment of a small set of diseases, including osteoporosis, comprising the administration of NH_2-OPD. It is noted that the instant disclosure defines "maintaining a healthy bone structure" as "prevention [prophylaxis] of clinically pathological conditions or diseases." The reference claim does not recite particular individuals to be treated or particular dosages. However, it would be obvious to one having ordinary skill in the art to administer the agent to patients in need with a reasonable expectation of success. As noted above, it would be within the scope of the artisan to optimize the dosage range through routine experimentation.

Reference claim 14 is drawn to the diagnosis, prophylaxis and/or treatment of bone and/or mineral metabolism disorders comprising the administration of NH_2-OPD. The claim does not recite the treatment of a patient having undergone corticosteroid treatment. Ringe teaches as set forth above. It would be within the scope of the artisan to administer the combination of NH_2-OPD and a vitamin D or derivative for any bone disorder, such as steroid-induced

osteopenia/osteoporosis (a metabolic bone disorder), wherein it is known to administer vitamin D alone, as discussed above.

Reference claim 14 is drawn to the diagnosis, prophylaxis and/or treatment of bone and/or mineral metabolism disorders comprising the administration of NH_2-OPD. The claim does not recite a method of post-treatment. Omeroglu teaches as set forth above. Omeroglu teaches as set forth above. It would be within the scope of the artisan to administer the combination of NH_2-OPD and a vitamin D or derivative for the post-treatment bone disorder, such as a fracture, wherein it is known to administer vitamin D alone, as discussed above.

Finally, it is noted that in addressing the enablement rejection raised by the previous examiner, Applicant opined that what the examiner intended was a utility rejection. As set forth above, Van Beek has amply demonstrated the utility of NH_2-OPD. To be clear, this rejection is based on lack of enablement for the full scope of the claims. In view of the foregoing, one of ordinary skill would require undue experimentation to use the invention commensurate to the scope of the claims.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh C. Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh C. Maier/
Primary Examiner
Art Unit 1623